REMARKS/ARGUMENTS

Claims 1-24 are pending, of which claims 16-24 are withdrawn.

The applicants and applicants' agents thank the Examiner and the Supervisory Patent Examiner for the telephonic interview on September 17, 2009. At the interview, the applicants' agent explained the distinction between the invention claimed in claim 1 and the cited references Chieng and Simamora, and why it would not be obvious for a skilled person to combine the two references to arrive at the subject matter of claim 1. The Examiners suggested that claim 1 be amended to clarify the distinction, and in particular, the initial placement of the drug in the polymer.

Claim 1 has been amended for clarification. Support for amended claim 1 can be found at least at paragraphs [0021], [0026], [0030], [0032], and [0040] and in FIG. 3 of the specification as filed.

Claims 6, 9, and 15 have been amended to define the recited abbreviations as requested by the Examiner. Support for the amendments can be found at paragraphs [0045], [0046] and [0034] of the specification as filed, respectively.

No new matter has been added.

Claims 1-8 and 10-15 are rejected in the Office Action under 35 USC 103(a) as being unpatentable over Chieng in view of Simamora and Liu. Claim 9 is rejected under 35 USC 103(a) as being unpatentable over Chieng in view of Simamora, Liu and Havermeyer. The Applicants respectfully traverse these rejections for at least the following reasons.

Claim 1, as amended, is directed to a method of forming a porous polymer, and recites "polymerizing a bicontinuous microemulsion comprising a first continuous phase comprising water, a second continuous phase comprising a monomer, and a surfactant copolymerizable with said monomer, to form a porous polymer." The polymer comprises "a matrix portion formed from said second phase and comprising a polymer matrix, and a water portion formed from said first phase and comprising water in interconnected pores defined by said matrix portion." Claim

1 further recites "a drug dispersed in at least said second phase" in the bicontinuous microemulsion, "such that, when said porous polymer is formed, said drug is initially dispersed in at least said matrix portion and is releasable from said matrix portion into said pores when said porous polymer is in contact with a liquid."

The Office Action states that "Chieng does not teach the inclusion of a drug dispersed in at least said polymer matrix and releasable therefrom" but that it would have been prima facie obvious "to use the porous polymer taught by Chieng and insert [*sic*] ocular drugs in the pores because ocular implants with pores containing drugs for controlled delivery are known in the art and have many advantages such as less frequent administration and lower side effects as taught by Simamora" (emphasis added).

The Applicants respectfully submit that the above combination of Chieng and Simamora suggested in the Office Action still fails to arrive at the method claimed in claim 1.

First, claim 1 recites a bicontinuous microemulsion comprising a drug. The drug is dispersed in at least the second continuous phase of the bicontinuous microemulsion prior to formation of the porous polymer by polymerizing the microemulsion.

Careful review of Simamora reveals that it discloses a Gelfoam (absorbable gelatin sponge) in the form of a matrix system for use as a drug carrier in an ocular device, and that the drug (pilocarpine) was "sorbed into the matrix" after the matrix system had been formed (see Simamora at page 210, section 2.1).

There is no disclosure or suggestion in Simamora, or any of the other cited references, that the drug should be dispersed in a bicontinuous microemulsion prior to polymerizing the microemulsion to form a porous polymer. There is also no disclosure or suggestion in Simamora or any of the other cited references that the matrix system should be formed by a bicontinuous microemulsion and thus having interconnected pores.

In fact, the prior art teaches away from dispersing a drug in a bicontinuous microemulsion prior to formation of the polymer.

One reason is that, as discussed in Simamora, delivery systems that are capable of releasing the drug in a prolonged manner are desirable (see Simamora at page 209, first paragraph of Introduction). In this regard, Simamora teaches the use of a retardant embedded in the pores of the matrix to prolong the release of the drug pilocarpine (see Simamora at page 210, last paragraph of left column). Chieng discloses that "bicontinuous microemulsion polymerization will give rise to the formation of open-cell polymeric materials" (see Chieng at page 1946, last sentence of CONCLUSIONS). The person skilled in the art would readily recognize that a drug dispersed in the pores of an open-cell polymeric material formed from a bicontinuous microemulsion disclosed in Chieng would be released quickly due to the interconnection between the open-cells formed from the continuous water phase, and would thus not disperse the drug in the interconnected pores in the open-cell polymer of Chieng.

Another reason is that Chieng and Simamora when combined teaches the skilled person away from dispersing the drug in the microemulsion prior to polymerization. Simamora teaches that a benefit of embedding the retardant in the pores after the Gelfoam has been formed is that it controls the release of the drug "without altering the biodegradability of the gelatine" (see Simamora at page 210, last paragraph of left column). Chieng teaches that the polyermizable ingredients in its microemulsion "are very reactive" (see Chieng at page 1943, third paragraph of left column), further suggesting to the skilled person that one or more of these polymerizable ingredients would react with a drug incorporated into the microemulson. Thus, the skilled person would not have dispersed the drug of Simamora in the bicontinuous microemulsion of Chieng.

It would also not be obvious to the skilled person that the drug should be dispersed in the continuous monomer phase of the bicontinuous microemulsion of Chieng, which will eventually be polymerized to form the matrix portion, as the skilled person would believe that it is difficult for the drug to release from the matrix portion formed from the monomer phase.

In view of the above, the skilled person would not have combined Chieng and Simamora in a manner to arrive at the method claimed in claim 1 of the present application.

However, the inventors of the present invention realized that the method of claim 1 can produce a polymer with improved drug release control due to the combination of dispersion of the drug in the matrix portion and the interconnection between the pores in the water portion.

Even though the drug travels faster in the interconnected water pores than in the matrix portion, a controlled and prolonged release can still be achieved as the drug is initially dispersed in at least the matrix portion and is releasable from the matrix portion into the pores. See, e.g. paragraphs [0024] to [0028] of the present application.

There is no disclosure or suggestion in Chieng and Simamora, either alone or in combination, that any benefits including those discussed above can be achieved when a polymer is prepared according to the method of claim 1.

None of the remaining cited references cures the above defects of Chieng and Simamora.

Therefore, it is respectfully submitted that the recited references, either alone or in combination, fail to disclose or suggest the method of claim 1, and withdrawal of the rejection of claim 1 under 35 USC 103(a) in view of the cited references is thus respectfully requested.

For similar reasons, it is respectfully requested that the rejections of claims 2-15, which depend from claim 1 directly or indirectly, also be withdrawn.

In addition, the Applicants note that the Examiner appears to have not considered the three references listed in the Information Disclosure Statement Forms PTO/SB/08B filed on September 11, 2008, December 16, 2008, and March 4, 2009 respectively. In each case, on the form attached with the present office action the Examiner has written "No Publication Date" beside the listed reference. It is assumed that this is the reason why the Examiner has not considered them. Applicants respectfully request the Examiner to consider these references for at least the following reasons.

37 CFR 1.98(3)(b)(5) requires that a "date" be identified for each publication. It does not require that the identified date be a "publication date." When a "publication date" is required, it is expressly indicated in 37 CFR 1.98(3). See, e.g., 37 CFR 1.98(3)(b)(2) and 1.98(3)(b)(4). Further, neither 37 CFR 1.97 nor 37 CFR 1.98 requires that a "publication date" be identified if the submitted document is not a publication.

Each of the three listed references is a communication in a related foreign application, and is not a prior art publication citable under 35 USC 102/103. Further, a date is identified for

each of the three listed references in the respective form. Thus, it is submitted that the submitted information in the above mentioned Forms PTO/SB/08B meets the requirements of both 37 CFR 1.97 and 37 CFR 1.98.

MPEP § 609 provides that "Once the minimum requirements of 37 CFR 1.97 and 37 CFR 1.98 are met, the examiner has an obligation to consider the information. There is no requirement that the information must be prior art references in order to be considered by the examiner" (emphasis added).

Accordingly, Applicants respectfully request the Examiner to consider these three references.

In view of the foregoing, favorable re-consideration of this application is earnestly solicited.

It is believed that no fees are required for filing this Response to Office Action. However, if any fees are required, the Director is authorized to charge said fees to Deposit Account No. 02-4550.

Respectfully submitted,

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